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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/163,199	09/30/1998	HITOSHI FUKUSHIMA	04783/026001	9722

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EXAMINER

GARCIA, MAURIE E

ART UNIT

PAPER NUMBER

1627

20

DATE MAILED: 02/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/163,199

Applicant(s)
Fukushima et al

Examiner
Maurie E. Garcia, Ph. D.

Art Unit
1627

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Nov 30, 2001

2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1, 7, and 8 is/are pending in the application

4a) Of the above, claim(s) _____ is/are withdrawn from consideration

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1, 7, and 8 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other:

DETAILED ACTION

1. Applicant's Response filed November 30, 2001 (Paper No. 19) is acknowledged. Claim 1 was amended, claims 3-6, 9-17, 20-26 and 18 were cancelled and no claims were added (please see next paragraph). Therefore, claims 1, 7 and 8 are pending.

2. It is noted that applicant refers to adding new claims 27-29 in the Response (page 4, top). However, the examiner could not find these claims listed anywhere in the Response.

3. Thus, claims 1, 7 and 8 are pending and are examined on the merits in this action.

Withdrawn Rejections

4. The previous rejections under 35 U.S.C. 112, second paragraph have been withdrawn in view of applicant's cancellation of claims and/or claim amendments. Maintained rejections are set forth below along with response to arguments. The previous rejections under 35 USC 102 have been withdrawn in view of applicant's amendments.

Maintained Rejections Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 8 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. These factors include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the level of one of ordinary skill;
- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and
- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1-2) The breadth of the claims and the nature of the invention: The claim is drawn to a “method of manufacturing a sensor device comprising a circuit having organic thin films formed on electrodes” where the device is further formed on a plastic substrate and the circuit comprises “poly-silicone thin film transistors”. Organic thin films are “printed” on the electrodes. No specific methodologies are set forth for preparing such

devices and no other structural limitations are set forth. Such represents very broad scope.

(3 and 5) The state of the prior art and the level of predictability in the art: Methods for manufacturing chemical sensors utilizing thin film transistors were known at the time of filing; however, only limited numbers of these methods were known and the specification gives no guidance to permit one of skill in the art to devise strategies for manufacturing a sensor as instantly claimed. The specifics on the manufacturing steps are sufficiently diverse and one of ordinary skill would not be able to predict such steps. Applicant's claim represents only an invitation to experiment regarding possible sensor set-ups.

For example, Ackley et al (5,719,033) discloses a chemical sensor including a thin film transistor (see Abstract). An "indicator film" is used as the sensing element which is *particularly* situated in order to provide a response, see columns 1-2 of the patent, especially column 1, line 55 through column 2, line 3.

(4) The level of one of ordinary skill: The level of skill would be high, most likely at the Ph.D. level. Such persons of ordinary skill in this art, given its unpredictability, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed.

(6-7) The amount of direction provided by the inventor and the existence of working examples: Applicants have provided *no* examples of manufacturing the sensors as instantly claimed. One of ordinary skill could not guess, *a priori*, how to carry out the claimed invention with regards to the manufacturing steps for creating "poly-silicone thin

film transistors” on a plastic substrate and then “printing” organic films thereon. The instant specification lacks an enabling disclosure as to how to make such sensors as the particulars on the location of the “poly-silicone thin film transistors”, electrodes/microelectrodes and positions of the “printed” organic thin films is not set forth.

(8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: In claim 8 there is only the broad recitation that a sensor device is manufactured comprising a circuit having organic thin films formed on electrodes where the device is further formed on a plastic substrate and the circuit comprises “poly-silicone thin film transistors”. No specific methodologies are set forth for the manufacture of such devices. Thus, the instant specification does not provide to one skilled in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in making and using the claimed invention. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the claimed invention.

Response to Arguments

7. Applicant's arguments filed November 30, 2001 have been fully considered but they are not found persuasive. The examiner's rationale is set forth below.

8. Applicant argues that claim 8 is enabled (Response, pages 6-7). Applicant refers to portions of the specification (and also the prior art) with respect to teachings of polysilicon thin film transistors. This is not enabling support for claim 8. The question at hand is how to carry out the claimed invention with regards to the manufacturing steps for creating "poly-silicone thin film transistors" on a plastic substrate and then "printing" organic films thereon. Thus, while the poly-silicone thin film transistors themselves may be well established in the art, it is the use of such in the instant invention that is not deemed to be enabled.

9. The examiner deems that the information set forth in the instant specification in no way teaches one of ordinary skill in the art how to ***make and use*** the invention. Applicant states that certain knowledge is within the skill of the art; however, it is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. The instant specification provides only a starting point, a direction for further research.

10. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of

unpredictability of the factors involved. See *In re Fisher*, 57 CCPA 1099, 427 F.2d 833, 839, 166 USPQ 18,24(1970). Additionally, the Board has held on the issue of unpredictability that "... the unpredictability of an art area alone may be enough to create a reasonable doubt as to the accuracy of statements in the specification." *Ex parte Singh*, 17 U.S.P.Q.2d 1714, 1716 (B.P.A.I. 1990). In applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624, 38USPQ 189, 191 (CCPA 1938).

11. Finally, note that the "predictability or lack thereof" in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art.

12. Thus, for these reasons, the above rejection of claim 8 under 35 USC 112, first paragraph is maintained.

New Rejections --- Necessitated by Amendment
Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. These factors include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the level of one of ordinary skill;
- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and
- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1-2) The breadth of the claims and the nature of the invention: Amended claim 1 is drawn to a “method of manufacturing a sensor device comprising a circuit having organic thin films formed on microelectrodes”. Organic thin films are “printed” on the electrodes. These films are made from a solution containing an “electro-conductive polymer”, “a solvent” and “a material selected from the groups consisting of enzymes,

antibodies, artificially synthesized molecules having recognizing functions similar to those of enzymes or antibodies, and mixtures thereof". No specific methodologies are set forth for preparing such devices and no other structural limitations are set forth. Such represents very broad scope.

(3 and 5) The state of the prior art and the level of predictability in the art: Methods for manufacturing chemical sensors utilizing thin film transistors were known at the time of filing; however, only limited numbers of these methods were known and the specification gives no guidance to permit one of skill in the art to devise strategies for manufacturing a sensor as instantly claimed. The specifics on the manufacturing steps are sufficiently diverse and one of ordinary skill would not be able to predict such steps. Applicant's claim represents only an invitation to experiment regarding possible sensor set-ups.

For example, Ackley et al (5,719,033) discloses a chemical sensor including a thin film transistor (see Abstract). An "indicator film" is used as the sensing element which is *particularly* situated in order to provide a response, see columns 1-2 of the patent, especially column 1, line 55 through column 2, line 3.

Most importantly, materials such as "enzymes, antibodies, artificially synthesized molecules having recognizing functions similar to those of enzymes or antibodies, and mixtures thereof" have very specific relativities and are sensitive to various chemical conditions. Thus, how to make (and use) a sensor device containing these moieties would be even more unpredictable.

(4) The level of one of ordinary skill: The level of skill would be high, most likely at the Ph.D. level. Such persons of ordinary skill in this art, given its unpredictability, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed.

(6-7) The amount of direction provided by the inventor and the existence of working examples: Applicants have provided *no* examples of manufacturing the sensors as instantly claimed. One of ordinary skill could not guess, *a priori*, how to carry out the claimed invention with regards to the manufacturing steps for “printing” organic films of solutions of “enzymes, antibodies, artificially synthesized molecules having recognizing functions similar to those of enzymes or antibodies, and mixtures thereof” on microelectrodes. The instant specification lacks an enabling disclosure of how to make such sensors as the particulars on how to make the films (and how to retain the activity of the moieties contained therein) is not set forth.

(8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: In amended claim 1 there is only the broad recitation that a sensor device is manufactured comprising a circuit having organic thin films printed on electrodes. *No* specific methodologies are set forth for the manufacture of such devices. Thus, the instant specification does not provide to one skilled in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in making and using the claimed invention. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary

skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the claimed invention.

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The newly added limitation in claim 1 of “artificially synthesized molecules having recognizing functions similar to those of enzymes or antibodies” is confusing. It is unclear as to applicant’s intent. How similar must these “recognizing functions” be to meet the limitation of the claim?

Status of Claims/ Conclusion

17. No claims are allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

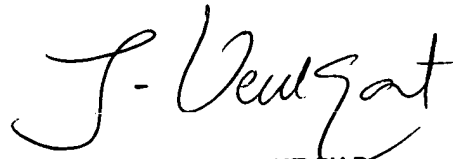
20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of

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a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie E. Garcia, Ph.D.
February 25, 2002


DR. JYOTHSNA VENKAT PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600